510(k) SUMMARY

510(k) Notification K 122609

DEC 2 1 2012

GENERAL INFORMATION

Applicant:
Venous Health Systems, Inc.
3270 Alpine Road
Portola Valley, CA 94028
U.S.A
Phone: 650-646-3327
Fax: 650-854-4772

Contact Person:
Rich Laguna
Director Quality Assurance & Operations
eMail: Rlaguna@venoushealth.com
Phone: 650-646-3327 extension 225
Fax: 650-854-4722

Date Prepared: August 24, 2012

DEVICE INFORMATION

The Vasculaire Compression System ("Vasculaire System") is a mobile, intermittent pneumatic compression system intended to provide sequential compression therapy to the patient's lower limb(s). The Controller is battery powered, provides selectable compression cycles and system monitoring of the compression therapy. The Sleeves are provided in a foot & calf or a calf only configuration for selectable lower limb(s) compression therapy.

Classification:
Compressible Limb Sleeve, 21 CFR§870.5800

Product Code:
JOW

Trade Name:
Vasculaire Compression System

Generic/Common Name:
Compressible Limb Sleeve

510(k) SUMMARY (Cont.)

PREDICATE DEVICE(S)

Venous Health Systems, Inc., Vasculaire Compression System (K103113)

Medical Compression Systems (MCS), WizAir DVT™ (K012994)

Medical Compression Systems (MCS), ActiveCare++ ®System (K060146)

Kinetic Concepts Inc. (KCI), PlexiPulse All-in-1® System (K944567/K981311)

INDICATIONS FOR USE

The Vasculaire Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
- Enhancing blood circulation
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers
- Treatment of chronic venous insufficiency
- Reducing edema

PRODUCT DESCRIPTION

The Vasculaire Compression System is a mobile, intermittent pneumatic compression system intended to provide compression therapy to the patient's lower limb(s). The Vasculaire Compression System includes three components: the Controller, the Sleeve and the Charger.

The Sleeve is a multiple-cell bladder intended to be attached directly to the lower limb(s). It is intended to provide compression to the tissue surrounding the vasculature. The Sleeve is provided in two configurations. The first configuration is a foot and calf Sleeve that provides sequential compression to the foot and calf. The second configuration is a calf only Sleeve that provides sequential compression to the calf. The Controller is connected to the Sleeve using two flange ports and can be mounted directly onto the Sleeve for a fully mobile system. The flange ports allow the air from the Controller to effect compression on the foot and calf zones independently. The Controller allows the user to select between foot and calf compression or a calf only compression. The Controller also allows the user to select compression cycles of approximately one to three cycles per minute. The Controller is a lightweight (less than 1 lb.), battery-powered, electromechanical control unit intended to provide and monitor the inflation cycle for enhanced circulation therapy. The Charger consists of a medical grade power supply and the table top docking station.

510(k) SUMMARY (Cont.)

SUBSTANTIAL EQUIVALENCE

The indications for use for the Vasculaire Compression System are equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the Vasculaire System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

There is no FDA performance standard required for the Vasculaire Compression System . All necessary bench testing was conducted on the modified Vasculaire System to support determination of substantial equivalence to the predicate devices. The testing performed included:

- ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices / Use & Design Risk analysis
- Specification bench and performance verification testing; airflow rate, operating pressure, pressure leakage/obstruction, venous peak flow velocity
- Packaging & Transit testing
- Software verification & validation
- IEC 60601-1; Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2; Medical electrical equipment - part 1: general requirements for safety 2 collateral standard: electromagnetic compatibility - requirements and tests
- BS EN ISO 10993-1:2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing and the FDA Guidance Document entitled, "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (G95-1)"

SUMMARY

The Vasculaire Compression System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2012

Venous Health Systems
Mr. Rich Laguna
3270 Alpine Rd.
Portola Valley, CA 94028

Re: K122609
Trade/Device Name: Vasculaire Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 8, 2012
Received: November 8, 2012

Dear Mr. Laguna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122609

Device Name: Vasculaire Compression System

Indications For Use:

The Vasculaire Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
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- Treatment of chronic venous insufficiency
- Reducing edema

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122609